

Appl. No. 10/506,612
Amendment dated: November 29, 2006
Reply to OA of: August 30, 2006

This listing of claims will replace all prior versions and listings of claims in the application.

Listing of Claims:

1(currently amended). A method of setting or adjusting a cardiac pacemaker in a patient diagnosed with cardiac asynchrony, which method comprises the steps of:

- i) implanting cardiac pacing wires into at least the right ventricle and the left ventricle of the heart of the patient,
- ii) continuously monitoring and recording the cardiac output, nominal stroke volume and/or arterial pressure of the patient on a beat-by-beat basis,
- iii) continuously monitoring and recording the respiratory cycle of the patient, and
- iv) adjusting the conduction delay between the electronic impulses to the cardiac pacing wires until a synchronization of respiratory changes with changes in the cardiac output, stroke volume or arterial pressure of the patient is obtained[[]], wherein when the synchronization of respiratory changes with changes in the cardiac output, stroke volume or arterial pressure of the patient is obtained, the optimal setting of the pacemaker is then determined by monitoring the stroke volume or arterial pulse pressure variation of the heart and selecting a pacemaker setting which provides an increased ventricle pre-load responsiveness.

2(original). A method as claimed in claim 1 wherein a cardiac pacing wire is additionally implanted into the right atrium of the patient's heart.

3(previously presented). A method as claimed in claim 1 wherein the arterial pressure of the patient is monitored by means of an arterial line and a pressure transducer.

4(previously presented). A method as claimed in claim 1 wherein the nominal stroke volume is derived by a method comprises the steps of

- (a) recording and storing the arterial blood pressure waveform of a patient from a blood pressure monitoring device over a period of time;
- (b) subjecting the waveform obtained in step (a) to a non-linear transformation that corrects for the variation of the characteristics of the arterial system with pressure;
- (c) subjecting the corrected waveform from step (b) to autocorrelation in order to derive the pulsatility and heart rate of the corrected waveform; and
- (d) calculating the nominal stroke volume from the pulsatility.

5(original). A method as claimed in claim 4 wherein the transformation in step (b) is effected using a look up table with the mean of the data being found and substrated.

6(previously presented). A method as claimed in claim 1 wherein the nominal stroke volume is derived by a method which comprises the steps of:

- (e) recording and storing the arterial blood pressure waveform of a patient from a blood pressure monitoring device over a period of time;
- (f) subtracting the mean of the waveform from step (e) and subjecting the data so obtained to autocorrelation;
- (g) transforming the data from step (f) into data which relates to the pulsatility and heart rate of the waveform; and
- (h) calculating the nominal stroke volume from the pulsatility.

7(original). A method as claimed in claim 6 wherein the transformation in step (f) is effected using a look up table, with the mean of the data then being subtracted.

8(previously presented). A method as claimed in claim 1 wherein the nominal stroke volume is derived by a method which comprises the steps of:

- (i) recording and storing the arterial blood pressure waveform of a patient from a blood pressure monitoring device over a period of time;
- (j) subjecting the data obtained in step (i) to Fourier analysis in order to obtain the modulus of the first harmonic; and
- (k) determining the nominal stroke volume from the modulus of the first harmonic obtained in step (j) and data relating to the arterial blood pressure and the heart rate.

9(previously presented). A method as claimed in claim 1 wherein the nominal stroke volume is derived by a method which comprises the step of :

- (l) recording and storing the arterial blood pressure waveform of a patient from a blood pressure monitoring device over a period of time;
- (m) subjecting the waveform obtained in step (l) to a non-linear transformation that corrects for the variation of the characteristics of the arterial system with pressure;
- (n) subjecting the data obtained in step (n) to Fourier analysis in order to obtain the modulus of the first harmonic;
- (o) determining the nominal stroke volume from the modulus of the first harmonic obtained in step (n) and data relating to the heart rate and optionally the arterial blood pressure.

10(original). A method as claimed in claim 9 wherein the transformation in step (m) is effected using a look up table, with the mean of the data then being subtracted.

11(previously presented). A method as claimed in claim 1 wherein the respiratory cycle of the patient is monitored by means of computer analysis of the arterial waveform, or by means of a strain gauge placed around the patient's chest.

12(previously presented). A method as claimed in claim 1 wherein the conduction delay between the individual electronic impulses to the different cardiac pacing wires is adjusted systematically using a predetermined matrix.

13(previously presented). A method as claimed in claim 1 wherein the cardiac output, nominal stroke volume and/or arterial pressure and the respiratory cycle of the patient are recorded and stored in an appropriately programmed computer and displayed on a display device integral with or connected to the computer.

14(previously presented). A method as claimed in claim 1 wherein the pacing rate of the electronic impulses to the cardiac pacing wires may be varied.

15(original). A method as claimed in claim 14 wherein the pacing rate is varied between 80 and 100 beats per minute.

16(currently amended). A method of adjusting a cardiac pacemaker having cardiac pacing wires implanted into at least the right ventricle and the left ventricle of the heart of a subject, which method comprises the steps of:

- (x) continuously monitoring and recording the cardiac output, nominal stroke volume and/or arterial pressure of the subject on a beat-by-beat basis,
- (xi) continuously monitoring and recording the respiratory cycle of the patient, and
- (xii) adjusting the conduction delay between the electronic impulses to the cardiac pacing wires until a synchronization of respiratory changes with changes in the cardiac output, stroke volume or arterial pressure of the subject is obtained[[.]], wherein when the synchronization of respiratory changes with changes in the cardiac output, stroke volume or arterial pressure of the patient is obtained, the optimal setting of the pacemaker

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is then determined by monitoring the stroke volume or arterial pulse pressure variation of the heart and selecting a pacemaker setting which provides an increased ventricle pre-load responsiveness.

17(original). A method as claimed in claim 16 wherein the cardiac pacemaker includes a cardiac pacing wire implanted into the right atrium of the subject's heart.

Claim 18(canceled).

19(previously presented). A method as claimed in claim 16 where the respiratory cycle of the patient is monitored by means of computer analysis of the arterial waveform, or by means of a strain gauge placed around the patient's chest.

20(previously presented). A method as claimed in claim 16 wherein the conduction delay between the individual electronic impulses to the different cardiac pacing wires is adjusted systematically using a pre-determined matrix.

21(previously presented). A method as claimed in claim 16 wherein the cardiac output, nominal stroke volume and/or arterial pressure and the respiratory cycle of the patient are recorded and stored in an appropriately programmed computer and displayed on a display device integral with or connected to the computer.

22(previously presented). A method as claimed in claim 16 wherein the pacing rate of the electronic impulses to the cardiac pacing wires may be varied.

23(original). A method as claimed in claim 22 wherein the pacing rate is varied between 80 and 100 beats per minute.

24(canceled).

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25(currently amended). An apparatus for setting or adjusting a cardiac pacemaker in a patient diagnosed with asynchrony and having cardiac pacing wires implanted into at least the right ventricle and the left ventricle, which apparatus comprises:

- (A) means for continuously monitoring and recording the cardiac output, nominal stroke volume and/or arterial pressure of the patient;
- (B) means for continuously monitoring and recording the respiratory cycle of the patient;
- (C) means for adjusting the delay between the electronic impulses to the pacing wires; and
- (D) means for determining when a synchronization of the respiratory changes with changes in the cardiac output, stroke volume or arterial pressure is obtained[.]; and

(E) means for determining the optimal setting of the pacemaker when the synchronization of respiratory changes with changes in the cardiac output, stroke volume or arterial pressure of the patient is obtained, wherein said means monitors the stroke volume or arterial pulse pressure variation of the heart and selects a pacemaker setting which provides an increased ventricle pre-load responsiveness.